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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,930	12/26/2001	Masayo Kondo	029650-111	8178

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1615	5

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/018,930	Kondo
Examiner	**Art Unit**
Gollamudi Kishore	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some* c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The preliminary amendment dated 12-26-01 is acknowledged.

Claims included in the prosecution are 1-19.

Claim Rejections - 35 USC § 112

1.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Line 3 of claim 17 recites a drug and line 8 recites chondroitin sulfate C; is chondroitin sulfate the drug? Clarification is requested. Also, this claim recites 'drug for a therapy and/or diagnosis', yet recites no diagnostic agent in the claim. Similar is the case with claims 18 and 19.

3. Claim 19 provides for the use of liposome composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 19 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of

a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless -**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

5. Claims 1-5, 7, 10-11, 13-16 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 636 363.

EP discloses a liposomal composition which selectively accumulates at the injured portion of vascular endothelium. The compositions contain a basic compound, a membrane forming phospholipid and a constituent of the membrane, cholesterol. Among the phospholipids taught are phosphatidylcholine, phosphatidylglycerol and acidic phosphatidic acid. The composition can further include surface modifying agents such as neuraminic acid (carboxyl group containing). The basic compounds include primary, secondary and tertiary amines and quaternary amines. According to EP the drug can be any drug and includes glycosaminoglycan, heparin; the diagnostic agents include X-ray

contrast agents (Note the abstract, page 4, lines 19-57, page 5, lines 21-42; and Examples, Example 3 in particular).

6. Claims 1-5, 7, 10-16, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 09 263579.

JP discloses liposomal composition containing the basic compound, piperidine derivative (claimed compound of the formula 2) to deliver a therapeutic agent to the diseased part. The drugs include polynucleotides, genes, antioxidants, glycosaminoglycans or diagnostic agents. The liposomes contain a phospholipid, and a constituent of the membrane, cholesterol. Among the phospholipids taught are phosphatidylcholine, phosphatidylglycerol and acidic phosphatidic acid. The composition can further include surface modifying agents such as neuraminic acid (carboxyl group containing compound) (note the abstract and the entire English translation).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

8. Claims 1-5, 7 and 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 636 363.

As pointed out above, EP discloses a liposomal composition which selectively accumulates at the injured portion of vascular endothelium. The compositions contain a basic compound, a membrane forming phospholipid and a constituent of the membrane, cholesterol. Among the phospholipids taught are phosphatidylcholine, phosphatidylglycerol and acidic phosphatidic acid. The composition can further include surface modifying agents such as neuraminic acid (carboxyl group containing). The basic compounds include primary, secondary and tertiary amines and quaternary amines. According to EP the drug can be any drug (Note the abstract, page 4, lines 19-57, page 5, lines 21-42; and Examples). Although EP does not exemplify the invention using an acidic phospholipid or using the surface modifier, neuraminic acid, it would have been obvious to one of ordinary skill in the art to prepare liposomal compositions containing these compounds from the guidance provided by EP with the expectation of obtaining similar results. EP does not teach specifically teach chondroitin sulfate as the glycosaminoglycan. However, in view of EP's teachings of the use any glycosaminoglycans, one of ordinary skill in the art would have been motivated to use any glycosaminoglycan with a reasonable expectation of success.

9. Claims 1-5, 7 and 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 09-263579 cited above.

As pointed out above, JP discloses liposomal composition containing the basic compound, piperidine derivative (claimed compound of the formula 2) to deliver a

therapeutic agent to the diseased part. The liposomes contain a phospholipid, and a constituent of the membrane, cholesterol. Among the phospholipids taught are phosphatidylcholine, phosphatidylglycerol and acidic phosphatidic acid. The composition can further include surface modifying agents such as neuraminic acid (carboxyl group containing compound). Although JP does not exemplify the invention using the acidic phospholipid, phosphatidic acid or using the surface modifier, neuraminic acid, it would have been obvious to one of ordinary skill in the art to prepare liposomal compositions containing these compounds from the guidance provided by EP with the expectation of obtaining similar results. JP does not teach specifically teach chondroitin sulfate as the glycosaminoglycan. However, in view of JP's teachings of the use any glycosaminoglycans, one of ordinary skill in the art would have been motivated to use any glycosaminoglycan with a reasonable expectation of success.

10. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 636 363 or JP 09-263579 cited above, further in view of Gold (6,465,188).

The teachings of EP and JP have been discussed above. Although these references teach the negatively charged neuraminic acid, they do not teach the inclusion of negatively charged fatty acids.

Gold while disclosing nucleic acid ligand complexes teaches that the efficiency of delivery of the complex may be optimized by using components which enhance the fusion of

the membranes and free fatty acids (carboxylate moieties) are fusion enhancing agents (note col. 14, line 66 through col. 15, line 20).

The inclusion of fatty acids in the compositions of EP or JP would have been obvious to one of ordinary skill in the art since free fatty acids enhance the delivery of nucleic acid by promoting fusion as taught by Gold.

10. Claims 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 636 363 in combination with either Schneider (6,258,378) and Malone (PNAS, vol. 86, pp.6077-6081, 1989).

The teachings of EP have been discussed above. Although EP teaches the use of either a primary, secondary, tertiary or quaternary amine, it does not teach claimed quaternary ammonium compounds in claim 6.

Schneider while disclosing liposomal compositions for the delivery of biologically active substances to target sites in the body of patients teaches that cationic lipids such as dimethylammoniumpropane (TAP) and dioleoyloxy propyl trimethylammonium chlorides (DOTMA) are useful in the formation of liposomes (note abstract, col. 6, lines 56-59).

Malone teaches that cationic lipids such as DOTMA enhances the liposome-mediated transfection of nucleic acids (note the abstract and the discussion).

The use of specific cationic ammonium lipids in the liposomes of EP would have been obvious to one of ordinary skill in the art since Schneider teaches their common use in the liposomes to deliver active agents to the target sites and Malone teaches that if the drug

involved is a nucleic acid, the cationic lipids enhance the transfection ability of the liposomes.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is

more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

June 30, 2003